



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

mk

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/475,721 12/30/99 REIMINK

M S16.12-0094

IM52/0913

WESTMAN CHAMPLIN & KELLY P A
SUITE 1600 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS MN 55402-3319

EXAMINER

HON. S

ART UNIT

PAPER NUMBER

b

1772
DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/475,721 | REIMINK ET AL. |
| | Examiner | Art Unit |
| | Sow-Fun Hon | 1772 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06/29/01.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-20 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation in claim 1 of "the polymer forming a structure substantially different from the structure of the substrate" is indefinite unless defined by the two different structures.
3. Claims 3, 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation in claims 3, 10, 15-19 of "can be bent" is indefinite. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).
4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the polymer material can form a slot, or a hole, which has no substance but is a void. In addition, a slot and a hole are not articles.

Art Unit: 1772

5. Claims 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the limitation in claims 10, 16, 17 of "extending the material beyond its elastic limit" means. Does it mean that the material is extended linearly to the point where its stress-strain behavior is beyond the linear portion of the stress-strain curve? Or does it mean that the material is bent to the degree where it fails to undergo elastic recovery (linear stress-strain behaviour) upon release of the bending load? Applicant is respectfully reminded that a crosslinked elastomer can undergo 180 ° bending and retain its elastic limit, and that it is the critical threshold of the amount of fatigue cycling under specific load-bearing conditions which causes the failure to maintain elastic recovery.

6. Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which component of the composite is bent. In addition, the limitation "without significant structural failure" is indefinite unless defined by a value or described by a term such as rupture or loss of full instantaneous elastic recovery.

7. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "diamond-like carbon coating" is unclear. Does it mean that the carbon coating has the diamond crystal structure?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pietsch et al. (US 4,778,461).

Pietsch et al. have a heart valve prosthesis consisting of three flexible curved cusps (leaflets), three corresponding commissure supports of a support ring. The upper region of the commissure consists of the cusp (leaflet) material and thus the cusp material is thickened to protect against flapping over (inversion) of the cusp (leaflet). Therefore the leaflet is thicker than the commissure. The wall thickness of the leaflet can be 50-1000 microns (column 2, lines 34-68). Metal and ceramics are taught to be materials used for the support ring, and hence the lower region of the commissure. The crosslinked silicone rubber (polydimethylsiloxane) is taught to be particularly suitable, having high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness (column 4, lines 55-68 and column 5, lines 1-15).

Crosslinked polyether-urethanes are also taught to be suitable with a low Shore A hardness and a high breaking strength (column 4, lines 20-55).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1772

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pietsch et al.

Pietsch et al. has been discussed above. The crosslinked silicone rubber (polydimethylsiloxane) is taught to be particularly suitable, having high fatigue strength in alternate bending as well as a high breaking strength of at least 8 N/mm² at a low Shore A hardness of 25-35, and an elongation at break of more than 400 % (column 4, lines 55-68 and column 5, lines 1-15).

Because Pietsch et al. teach that the crosslinked elastomer has high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness, and an elongation at break of more than 400 %, the examiner has taken the position that the leaflet of Pietsch et al. can be bent about 60 degrees for about 400 million cycles without significant structural failure.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pietsch et al. as applied to claims 18-19 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

In addition, Pietsch et al. has been discussed above, and fail to teach a diamond-like carbon coating over at least a portion of the silicone or urethane polymer.

Sumimoto Electric Co. teaches that coating by carbon or diamond of an artificial heart valve comprising polymer such as silicone polymer, polyurethane or PTFE gives the valve good antithrobosis property and good durability.

Art Unit: 1772

Because Sumimoto Electric Co. teaches that coating by carbon or diamond of an artificial heart valve gives the valve good antithrobosis property and good durability, it would have been obvious to one of ordinary skill in the art to have used the teaching of Sumimoto Electric Co. in the invention of Pietsch et al. in order to obtain a heart valve with good antithrobosis property and improved durability.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

84
09/06/07